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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,628	10/06/2000	G. Grady McBride	5259-04700	1875

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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

12 -

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/684,628

Applicant(s)

MCBRIDE ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-107 and 283 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 15-25, 27-32, 37, 42-46, 48-53, 57, 60-67, 69-77, 81-84, 86, 88-99, 101-107, and 283 is/are rejected.
- 7) ☒ Claim(s) 3, 6-14, 26, 33-36, 38-41, 47, 54-56, 58, 59, 68, 78-80, 85, 87 and 100 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 5, 20, 21, 23-25, 27-29, 37, 42, 43, 46, 48, 57, 65, 66, 91-94, 96, 105, and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by Montague et al. (5,688,272). With respect to claims 1, 2, 5, 20, 21, 23-25, 27, 37, 42, 43, 46, 48, 57, 65, and 66, Montague discloses, in figures 6 and 7, a connector (204) or transverse connector (of bone or the spine) for an elongated member (R) having a body (30), a first opening (32) in the body configured to hold the elongate member, an engager (47) with a surface of a cam system (40, 43) or an engaging mechanism (40, 43) with a portion (40) angulated within the body substantially perpendicular to a longitudinal axis of the body, and a cam system opening (37) in communication with the first opening, where removal of the cam system is inhibited by threads (at 37), where a drive tool (e.g., an Allen head wrench—see col. 9, lines 5-10) is used to rotate the cam system (at the engager). With respect to claims 91-94, 96, 105, and 106, Montague et al. disclose, in figure 7, a bone stabilization system (10) and a method of attaching a transverse

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connector to an elongated member, where the system and method include first and second elongated members (R), first and second fixation elements (200), and a connector (11) of fixed length and having a cam system (12, 40, 43) coupling the connector to the elongated members.

3. Claims 1, 15-19, 22, 42, 45, 49, 54, 60-64, 67, 69, 70, 71, 77, 81, 86, 88-91, 97-99, 101-104, and 283 are rejected under 35 U.S.C. 102(e) as being anticipated by Troxell et al. (6,283,967). With respect to claims 1, 15-19, 22, 42, 45, 49, 54, 60-64, 67, 69, 70, 71, 77, 86, 88-91, 97-99, and 283, Troxell et al. discloses, in the figures, a connector and a method of forming a connector, where the connector and the method include a substantially unbendable (but bendable, nonetheless) body (10) with first and second sections (16, 18), an indentation (32), and a fastening system (44) or fastener, first and second openings (at 22 and 26) in the body for receiving elongated members (12, 14), and a cam system (94) in communication with the first opening, positioned between the first and second openings, and configured to rotate or extend an engager (102) into the first opening, and a cam system opening (92), where the longitudinal axis of the cam system is substantially perpendicular to the longitudinal axis of the body, where the connector is a transverse connector of a bone or spinal stabilization system, and where the position of cam system within the cam system opening gives a visual indication of engagement. With respect to claims 101-104, Troxell et al. disclose a method of forming a connector (18 with 94), where a threaded connection is not formed between a cam system (16 with 94) and a body (18) of the connector, and where the

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method includes inhibiting removal of the cam system (at 24) from a cam system opening (28) through the application of a fastening system or setscrew (44).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 4, 27, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. in view of Tornier et al (5,662,651). Montague et al. disclose the invention substantially as claimed, but do not disclose a connector with an opening surface that contacts an elongated member, where the surface is textured. Tornier et al. teach, in figure 1, a connector (3) with a textured surface (3d) for contacting an elongated member. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Tornier et al., to texturize the opening surface of the connector of Montague et al. Such a modification would make for a more

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secure connection (without rotation of the elongated member) between the connector and elongated member.

6. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. Montague et al. disclose the invention substantially as claimed, but do not specifically disclose the rotation ranges of the cam system as claimed.

Nevertheless, it would have been a matter of design choice to dimension the engaging mechanism, so that the cam system has a rotation range of claimed. Such a choice would be dependent upon the size of an elongated member required for a surgical procedure.

7. Claims 50-52, 72-76, and 82-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Troxell et al. Troxell et al. disclose the invention substantially as claimed, but do not specifically disclose the rotation ranges of the cam system as claimed and distances between elongated members as claimed. Nevertheless, it would have been a matter of design choice to dimension the transverse connector, so that the cam system has a rotation range of claimed. Such a choice would be dependent upon the size of an elongated member required for a surgical procedure. Also, it would have been a matter of design choice to dimension the connector, so that the distances between elongated member are as claimed. The choice would be dependent upon the dimensions and location of the surgical site receiving the connector.

8. Claim 95 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. Montague et al disclose the invention substantially as claimed but

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do not disclose elongated members that have portions, which are unitary, bent, and contoured. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include such elongated members. Such elongated members can be applied in spinal fixation, depending on the degree of curvature in a vertebral column.

Allowable Subject Matter

9. Claims 3, 6-14, 26, 33-36, 38-41, 47, 54-56, 58, 59, 68, 78-80, 85, 87, and 100 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses, inter alia, a connector with a body, an engager, a cam system, first and second elongated members, and first and second fixation elements, where the engager has a textured surface for contacting an elongated member; where the connector includes a vibrational, drive tool, or pin indicator that the cam system is engaged with the body, where the cam system is angulated within the connector greater than 45 degrees relative to a longitudinal axis of the connector and less than perpendicular, where the opening has an open side that allows an elongated member to be top loaded onto the

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connector, and where the fastening system for section of the connector comprises a collet and a collar.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

11. The objections and the rejection of claims based on 35 U.S.C. 112 are hereby withdrawn.

The amendment has overcome the rejection of claims under 35 U.S.C. 102 and based on the reference Wagner have been overcome.

The arguments with respect to the rejection of claims under 35 U.S.C. 102 and 103 and based on the reference Montague et al. have been considered, but are not persuasive and are also moot in view of new grounds of rejection. That is, see the rejections above, where a "cam system" has been defined in include, for instance, element 40 in Montague et al. as opposed to element 12 cited in the Office action of September 15, 2003. "Cam system" can be defined by various, interacting, sliding parts as seen in Montague et al.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

March 23, 2004